

## VIOLATIVE SALES OF PRESCRIPTION DRUGS\*

**5744. Raupentina tablets, Amphocaps capsules, and solution of liver and iron with vitamins.** (F.D.C. No. 40476. S. Nos. 28-655 M, 50-164/5 M, 72-678 M.)

INFORMATION FILED: 4-25-58, E. Dist. Pa., against the Professional Products Co., a partnership, and Raymond Steiner, a partner.

SHIPPED: Between 11-7-56 and 2-14-57, from Pennsylvania to Connecticut, California, and Illinois.

LABEL IN PART: (Btl.) "100 No. 1134 RAUPENTINA (Brand of Rauwolfia Serpentina) 50 Mgm. USUAL DOSAGE: 2 to 3 tablets daily, administered morning and evening. CAUTION: Federal law prohibits sale or dispensing without prescription," "AMPHOCAPS \* \* \* Each capsule contains a total of: Thyroid 3 grs. Amphetamine Sulfate 15 mgm. Phenobarbital  $\frac{1}{4}$  gr.," and "30 cc Multiple Dose Vial LIVER, IRON, with Vitamins B-1 and B-12."

CHARGE: *Raupentina tablets*. 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes and conditions for which it was intended; and 503(b)(1)—the article was a drug within the meaning of 503(b)(1)(C) and, while being held for sale by the defendants, was dispensed by the defendants without a prescription from a licensed practitioner.

*Amphocaps capsules*. 503(b)(4)—the article was subject to the provisions of 503(b)(1) and its label failed to bear, prior to its dispensing, the statement "Caution: Federal law prohibits dispensing without prescription."

*Solution of liver and iron with vitamins*. 501(c)—the strength of the article, when shipped, differed from that which it purported or was represented to possess since each 2 cubic centimeters of the article was represented as containing 30 micrograms of vitamin B<sub>12</sub> and 100 milligrams of thiamin hydrochloride, whereas each 2 cubic centimeters of the article contained less than those amounts of vitamin B<sub>12</sub> and thiamin hydrochloride.

PLEA: Nolo contendere.

DISPOSITION: 11-7-58. The court imposed a fine of \$1,000 against the defendants jointly, and placed them on probation for one year.

## DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS †

**5745. Various drugs.** (F.D.C. No. 42230. S. Nos. 4-841/54 P.)

QUANTITY: 2 147-capsule btl. of *glucosamine parenteral tetracycline*; 2 147-capsule btl., and 62 boxes, each containing 2 6-capsule btl., and 30 boxes, each containing 2 10-cc. btl., of *Cosa-Tetracyn*; 1 169-capsule btl., and 20 boxes, each containing 2 4-capsule btl., of *Cosa-Signemycin*; 2 72-capsule btl., and 49 boxes, each containing 2 4-capsule btl., of *Cosa-Terramycin*; 1 6-oz. btl., and 48 boxes, each containing 2 10-cc. btl., of *Signemycin*; 1 14-oz. btl., 1 ctn. of 50 boxes of 2 10-cc. btl. each, 1 ctn. of 48 boxes of 2 10-cc. btl. each, and 1 ctn. of 28 boxes of 2 10-cc. btl. each, of *Tetrabon V*; 1 20-capsule btl. of *Sigmamycin V*; 1 169-capsule btl. of *Cosa-Tetrastatin*; 1 37-capsule btl. of *Tetracyn V*; 1 1,200-capsule btl. of *Terramycin*; 1 49-capsule btl. of *Achromycin V*; 2 75-capsule btl., and 1 150-tablet btl., of *urobiotic capsules Cosa-Terramycin*; and 1 bag containing 12 24-tablet btl.,

\*See also No. 5741.

† See also Nos. 5741, 5744.

and 1 bag containing 15 24-tablet btl., of *Tetracydin*, at Alexandria, Va., in possession of Mount Vernon Service Pharmacy, Inc.

SHIPPED: Between 1-2-58 and 9-4-58, from Brooklyn and Pearl River, N.Y.

RESULTS OF INVESTIGATION: The bottles containing the articles were physician's sample bottles, some of which bore the physician's sample statement, some of which had such statement removed, and some of which were unlabeled.

LIBELED: 10-15-58, E. Dist. Va.

CHARGE: *Cosa-Terramycin capsules*. 502(a)—while held for sale, the label statement "Professional Sample" appearing on the labeled bottles was false and misleading as applied to the article which was not intended for use as physician's samples, but for repackaging and distribution in an uncertified condition and with incomplete labeling; 502(b) (1)—the article, contained in an unlabeled bottle, failed to bear a label containing the name and address of the manufacturer, packer, or distributor; 502(b) (2)—the article, contained in the unlabeled bottle and in the labeled bottles, failed to bear an accurate statement of the quantity of contents.

*Terramycin*. 502(b) (1)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(b) (2)—the article failed to bear a label containing an accurate statement of the quantity of contents; 502(e) (2)—the article failed to bear the common or usual name of each active ingredient; 502(f) (1)—the labeling of the article failed to bear adequate directions for use; and 503(b) (4)—the article was a drug subject to 503(b) (1), and its label failed to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription."

*Urobiotic capsules Cosa-Terramycin*. 502(b) (2)—while held for sale, the article failed to bear a label containing an accurate statement of the quantity of contents; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient.

*Cosa-Tetracyn, Cosa-Signemycin, Signemycin, Tetrabon V, and Cosa-Tetracyn*. 502(a)—the label statement "Professional Sample" appearing on the labels of the articles, while held for sale, was false and misleading as applied to the articles which were not intended for use as physician's samples, but for repackaging and distribution in an uncertified condition and with incomplete labeling.

*Glucosamine parenteral tetracycline, Sigmamycin V, Cosa-Signemycin, Cosa-Tetrastatin, Tetracyn V, Achromycin V, Cosa-Tetracyn, Signemycin, Tetracydin and Tetrabon V*. 502(1)—while held for sale, the articles contained tetracycline and were not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 2-25-59. Default—destruction.

#### DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

5746. Abundavita vitamin tablets, Abundavita mineral tablets, Abundavita protein tablets, and Abundalax tablets. (F.D.C. No. 42151. S. Nos. 16-169/72 P.)

INFORMATION FILED: 8-18-58, E. Dist. Ky., against J. Vincent Reed, D.C., Newport, Ky.

\*See also Nos. 5744, 5745.